

Patient card for the safe application

PATIENT

This patient card was prepared for medicinal products that contain zoledronic acid in order to reduce the risk of the occurrence of osteonecrosis of the jaw and to increase the benefit-risk balance of medicinal products that contain zoledronic acid.

This patient reminder card should ensure that the patients know and take into consideration the special safety requirements.

In addition, the patient is to be given the instructions for use for medicinal products that contain zoledronic acid. Please read through these carefully before treatment, they contain further important information.

If you have questions in this regard or are uncertain about anything, please ask your physician or nurse.

Be sure to inform your dentist of the treatment with medicinal products that contain zoledronic acid at your next appointment. You can do this by having your attending physician complete the detachable section of the reminder card for the patient and then giving the section to your dentist.

OSTEONECROSIS IN THE JAW AREA

This patient card contains important safety information that you need to be aware of before and during treatment of cancer-related conditions* with zoledronic acid.

Your physician has recommended that you receive zoledronic acid [injections/infusions] in order to prevent complications in the bones (e.g. bone fractures) due to bone metastases or bone cancer and/or to reduce the calcium level in the blood of adult patients if this level is too high due to a tumour*.

An undesirable effect, osteonecrosis of the jaw (bone damage to the jaw), has been uncommonly observed in patients who received zoledronic acid for the treatment of cancer-related conditions*. Osteonecrosis of the jaw can also occur after the treatment has been stopped.

* Indications may vary depending on the authorisation in your local country

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Information for your dentist

DENTIST

Contact data

(To be completed by the attending physician)

Name of the patient _____

Telephone number _____

E-Mail _____

Start of the treatment with zoledronic acid _____
(Oncological indication)

Name of the physician _____

Telephone number _____

E-Mail _____

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You should take several precautions in order to reduce the risk of developing osteonecrosis of the jaw:

Before starting treatment:

- Ask your doctor to tell you about osteonecrosis of the jaw before you start treatment.
- Check with your doctor whether a dental examination is recommended before you start treatment with medicinal products that contain zoledronic acid.
- Inform your doctor/nurse (health care professional) if you have any problems with your mouth or teeth.

Patients undergoing dental surgery (e.g. tooth extraction), who do not receive routine dental care, who have gum disease, who are smokers, who get different types of cancer treatments, or who were previously treated with a bisphosphonate (for the treatment and prevention of bone diseases) may have a higher risk of developing osteonecrosis of the jaw.

While being treated:

You should maintain good oral hygiene. If you have a dental prosthesis (denture), make sure that it fits correctly and receive routine dental check-ups.

- If you are under dental treatment or will undergo dental surgery (e.g. tooth extraction), inform your physician and tell your doctor that you are being treated with medicinal products that contain zoledronic acid.
- Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, non-healing of sores, or a discharge in the mouth or jaw area as these could be signs of osteonecrosis of the jaw.

Read the package leaflet for further information.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet.

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Information for your dentist

DENTIST

This information for the dentist is an officially supported action intended to ensure that members of the healthcare professions know and take into consideration the special safety requirements associated with the prescription and use of medicinal products that contain zoledronic acid. The patient whose name appears on the front is being treated with zoledronic acid [injections/infusions] in order to prevent complications in the bones (e.g., bone fractures) due to bone metastases or bone cancer or to reduce the level of calcium in the blood of adult patients if a tumour is causing excess calcium in the blood*. There have been uncommon (<1 of 100 patients) observations of osteonecrosis of the jaw (ONJ) in patients receiving zoledronic acid [injections/infusions] for the treatment of cancer-related diseases*. This can also occur after the treatment has been terminated.

Before starting treatment, patients with risk factors for osteonecrosis of the jaw should undergo a dental examination. Treatment should not be started in patients with unhealed lesions of the soft tissue in the mouth.

Where possible, invasive procedures in the mouth area should be avoided in this patient during the treatment with medicinal products that contain zoledronic acid. Dental treatments can lead to exacerbation in patients who have developed osteonecrosis of the jaw during treatment with a medicinal product that acts on the bones.

If an invasive procedure is necessary, please contact the treating physician to discuss suitable, low-risk treatment options (the physician's contact data is given on the front of this card).

ONJ treatment should be closely coordinated with the physician and a dentist/oral surgeon with expertise regarding ONJ.

Further copies of the educational material can be downloaded on the website of the marketing authorisation holder:

<https://www.denkpharma.com>

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